IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	C.A. No. 15-1155 (SLR) (SRF)
v.	)	
MYLAN PHARMACEUTICALS INC. and MYLAN, INC.,	)	
Defendants.	)	

ANSWERING BRIEF IN OPPOSITION TO MYLAN'S MOTION TO DISMISS

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NATURE AND STAGE OF PROCEEDINGS

On December 16, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., and Rhodes Technologies ("Purdue") timely filed this Hatch-Waxman suit in response to Mylan Pharmaceuticals Inc. and Mylan, Inc.'s ("Mylan") "Notice of Paragraph IV Certification" in which Mylan stated its intent to obtain FDA approval for generic OxyContin® before Purdue's U.S. Patent No. 9,073,933 ("the '933 patent") expires. (D.I. 1 at ¶ 32.) The '933 patent is the only asserted patent. On April 5, 2016, Mylan moved to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) on the ground of collateral estoppel. (D.I. 23.)[1] Limited document discovery has occurred to date, and fact discovery does not conclude until June 23, 2017. Purdue hereby opposes Mylan's motion.

SUMMARY OF ARGUMENT

1. Mylan's motion to dismiss should be denied. The '933 patent issued recently, in July 2015, and has *never* been adjudicated. The patent—which includes only product claims and process claims—relates to oxycodone API with low amounts of a potentially genotoxic impurity that had long been a persistent component of oxycodone. Each of the claims requires the presence of "8α," a new molecule that Purdue discovered was the source of the impurity's persistence. These 8α limitations, and others, have never been addressed before.

Mylan nonetheless contends this case should end before it even begins, arguing that two prior actions involving different types of claims, with different claim language, already decided

[1] Mylan's Opening Brief in Support of Their Motion to Dismiss (D.I. 24) is cited as "Br." The '933 patent is attached as Exhibit 1 to D.I. 25 and cited herein as the "'933 patent." Exhibits A-B to Mylan's brief and Exhibits 1-11 to the attorney declaration in support thereof (D.I. 25) are cited as "Br. Ex. __." Exhibits 1-4 to the present opposition are cited as "Opp. Ex. __." To the extent the Court takes judicial notice of Exhibits 1-11 of Mylan's brief, Purdue requests that the Court take notice of Exhibits 1-4 attached to this opposition. Like Mylan's Exhibits 5-6, Purdue's Exhibits 1 and 4 are copies of public filings in court proceedings. Like Mylan's Exhibit 7, Purdue's Exhibits 2 and 3 are portions of the public file history of the '933 patent.

the issues here. Not only is one of those actions still ongoing, but neither action governs here. Among other differences, for validity purposes, none of the adjudicated claims requires 8α. This fact alone precludes collateral estoppel. Additional limitations further distinguish the claims.

For instance, for the product claims of the '933 patent (*e.g.*, independent claims 1 and 16), Mylan relies on the prior action involving Purdue's "low-ABUK patents." But as Mylan well knows, having participated in that case and supported the obviousness grounds adopted there, those courts *disregarded* 8α, for two reasons inapplicable here. *First*, the adjudicated low-ABUK claims were all product-by-process claims, and the courts disregarded the 8α limitations based on principles specific to product-by-process claims.[2] Here, by contrast, no claim is a product-by-process claim. *Second*, those courts held that identification of 8α was not necessary to obtain the products claimed in the low-ABUK patents: oxycodone with low amounts of the impurity. Here, by contrast, the '933 product claims recite oxycodone that "comprises" 8α—products that the prior adjudication did not address.

The processes claimed in the '933 patent (*e.g.*, independent claim 10) likewise require 8α—they recite the step of removing 8α from an oxycodone base. Mylan again invokes the prior adjudication of the low-ABUK patent claims, but again ignores that those courts disregarded 8α on grounds inapplicable here. As for the process claims in Purdue's then-pending "Chapman application" that were held obvious—the other action Mylan invokes—those claims did not recite 8α *at all* and thus did not decide the issues here. Indeed, the Federal Circuit indicated in that action that claims specifying 8α—like the '933 claims—would be patentable.

Mylan glosses over these (and other) differences, contending that the prior actions

[2] A "product-by-process" claim is a claim to a product "in which the product is defined at least in part in terms of the method or process by which it is made." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006).

resolved the validity of the '933 patent claims because those actions concerned "the same product," "the same subject matter," and "the same issue." (*E.g.*, Br. 2, 8, 10, 17.) Mylan misapplies the law and misstates the facts. As to the law, claims, not products, patents, or general subject matters, are evaluated for invalidity. As to the facts, although the patents and application at issue in those prior actions relate to the '933 patent and share the same specification, the claims are materially different, and those differences were *not* at issue or actually adjudicated in the prior actions.

2. Mylan's motion should also be denied because it is premature. Applying collateral estoppel to different patent claims from those previously adjudicated requires intense factual analysis. Mylan's own cited cases applying collateral estoppel to unadjudicated patent claims did so no earlier than summary judgment or as late as appeal—not on a motion to dismiss before claim construction or full discovery. Mylan's motion also ignores Purdue's pending petition for rehearing en banc regarding the prior decision on the low-ABUK patents. If that decision is reversed by the Federal Circuit (or the Supreme Court), that purported basis of collateral estoppel would be moot. At minimum, therefore, the Court should not decide Mylan's motion until that case is finally resolved.

COUNTERSTATEMENT OF FACTS

A. Purdue's '933 Patent and this Lawsuit

Purdue's OxyContin® is the first-ever FDA-approved abuse-deterrent, extended-release oxycodone product. It is a medically and commercially successful treatment for severe pain. Purdue scientists developed and patented numerous inventions relating to OxyContin®, including the '933 patent, which is directed to oxycodone API with very low levels of a potentially genotoxic impurity, 14–hydroxycodeinone ("14-hydroxy"). 14-hydroxy belongs to a class of potentially dangerous compounds known as alpha, beta unsaturated ketones ("ABUKs").

The '933 patent is directed to oxycodone API compositions with low levels of 14-hydroxy and processes for making the same. Each of the claims recites 8α in some fashion. The claimed compositions require, *inter alia*, the presence of 8α, and the claimed processes require, *inter alia*, the step of removing 8α from an oxycodone base composition.

The '933 patent contains three independent claims. It is undisputed that independent claims 1 and 16 are product claims. (Br. 1, 15.) Claims 1 and 16 recite as follows:

> 1. An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.
>
> 16. An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, less than 5 ppm of codeinone, and less than 25 ppm of 14-hydroxycodeinone.

Independent claim 10 is undisputedly a process claim. It recites as follows:

> 10. A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

In its complaint, Purdue asserts that Mylan infringes "one or more claims of the '933 patent, including but not limited to independent claims 1 and 16." (D.I. 1 at ¶ 36.)

B. The *Teva* Action

Purdue previously brought Hatch-Waxman litigation against Teva Pharmaceuticals, USA, Inc. and other defendants (including Mylan) in the U.S. District Court for the Southern District of New York for infringement of the low-ABUK patents (U.S. Patent Nos. 7,674,799, 7,674,800, and 7,683,072). The claims of the '799 and '072 patents are directed to oxycodone API having less than 25 ppm 14-hydroxy, "wherein at least a portion of the 14[-]hydroxy[] is derived from 8α[]." (Br. Ex. A.) Claim 1 of the '072 patent is exemplary:

> 1. An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14:hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.

The asserted claims of the '800 patent recite "[o]xycodone salt prepared according to the process of claim 1" or claim 57, and additional limitations. Claim 1 is representative of the processes:

> 1. A process for preparing an oxycodone salt substantially free of 14-hydroxycodeinone, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α,14-dihydroxy-7,8-dihydrocodeinone component;
>
> (b) incubating the mixture under conditions suitable to convert the oxycodone free base to an oxycodone salt, wherein said conditions promote an acid catalyzed dehydration consisting of conversion of the 8α,14-dihydroxy-7,8-dihydrocodeinone component to 14-hydroxycodeinone; and
>
> (c) preferentially removing the 14-hydroxycodeinone from the oxycodone salt.

The case against Teva proceeded first. The district court held that all the asserted claims were product-by-process claims. *See Purdue Pharma LP. v. Teva Pharms., USA, Inc.*, 994 F. Supp. 2d 367, 403 n.6 (S.D.N.Y. 2014); *see also Purdue Pharma LP v Epic Pharma LLC*, 811 F.3d 1345, 1351-54 & n.2 (Fed. Cir. 2016). The court determined that Teva infringed the asserted claims and that the claims satisfied the disclosure and claiming requirements of 35 U.S.C. § 112, but that the claims were invalid for obviousness under 35 U.S.C. § 103. *Purdue*, 994 F. Supp. 2d at 409-10, 438. The court acknowledged that Purdue discovered 8α as "the source of the 14-hydroxy problem" and that 8α was "a compound the prior art never identified." *Id.* at 387, 397; *see also id.* at 401 ("8α was unknown in the prior art: its very existence was unexpected"); *id.* at 405 (referring to "the discovery of 8α"). Nonetheless, in assessing obviousness, the court ignored the derived-from-8α limitations in the '799 and '072 patent

claims and related limitations reciting 8α in the '800 patent claims. The court held that those "process limitations" in product-by-process claims are "disregarded" in the obviousness inquiry. *Id.* In the remaining suits against Mylan and the other defendants involving the same claims, the district court entered judgment of collateral estoppel of obviousness.

Purdue appealed the obviousness ruling to the Federal Circuit, which affirmed. Adopting arguments urged by the appellees including Mylan, the Federal Circuit relied on principles specific to product-by-process claims, holding that "the district court did not err in disregarding the 8α limitations" in assessing the obviousness of product-by-process claims. *Purdue*, 811 F.3d at 1351-55. Again at appellees' urging, the Court also held that, because the claimed product was "oxycodone API with low ABUK levels," knowing "the 14-hydroxy was derived from 8α" was irrelevant to obviousness and disregarded the role of 8α on this ground too.[3] *Id.* at 1352-53.

On April 1, 2016, before Mylan filed the motion currently before the Court, Purdue petitioned for rehearing en banc of the Federal Circuit panel's decision in the *Teva* appeal. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, No. 14-1294 (Fed. Cir. Apr. 1, 2016), D.I. 187 (attached as Opp. Ex. 1). Three amicus briefs in support of the petition have been submitted. *Id.*, D.I. 204-06. As of this filing, Purdue's petition remains pending. If Purdue's petition is unsuccessful, it intends to seek review by the Supreme Court.

C. The Chapman Interference Proceeding

The low-ABUK patents and the '933 patent are continuations of an earlier application referred to as the Chapman application. During an interference proceeding involving that

[3] Mylan incorrectly states that the Federal Circuit held "the low-ABUK patents" invalid. (Br. 2; *accord id.* at 9 (referring to "the now-invalid low-ABUK patents").) Only claims 3 and 19 of the '799 patent, claims 30-34 and 76-79 of the '800 patent, and claims 1, 4, and 5 of the '072 patent were at issue in *Teva* and held invalid. *See Purdue*, 811 F.3d at 1350-51 & n.1; (Br. Ex. A).

application, the PTO found that independent claim 96 of the application and dependent claims thereof were invalid as obvious, and the Federal Circuit affirmed. *See Chapman v. Casner*, C.A. No. 08-1427, 315 F. App'x 294, 295 (Fed. Cir. Mar. 11, 2009); (Br. Ex. 4-5).

All of the adjudicated Chapman application claims are process claims. None recites 8α. Independent claim 96 is representative. It recites:

> 96. A process for preparing oxycodone or an oxycodone salt, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone, solvent and an acid;
>
> (b) incubating the mixture under conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxy[]; and subsequently
>
> (c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxy[] to oxycodone.

Id. In holding the claims at issue unpatentable as obvious, the PTO and subsequently the Federal Circuit relied on the lack of any reference in the claims to 8α as "the source of the 14-hydroxy." *Purdue*, 811 F.3d at 1349 (citing *Chapman*, 315 F. App'x at 297 (referring to 8α as "8á" and 8β as "8â")). Because the prior art disclosed conditions under which 8β (another 14-hydroxy precursor) converts to 14-hydroxy, the claims were obvious over the prior art. *Id.* In upholding this result, the Federal Circuit suggested that if the claims had instead recited 8α, they would likely be nonobvious. *See id*. (citing *Chapman*, 315 F. App'x at 297) (explaining claims held invalid in *Chapman* because they "did not specify the source of the 14-hydroxy").

ARGUMENT

I. THE '933 CLAIMS ARE NOT SUBJECT TO COLLATERAL ESTOPPEL

A. Collateral Estoppel Requires Adjudication of the Same or Substantially the Same Patent Claims

Dismissal of a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) based on

an affirmative defense such as collateral estoppel is permitted only where entitlement to the defense is "apparent on the face of the complaint." *Rycoline Prods. v. C & W Unlimited*, 109 F.3d 883, 886-87 (3d. Cir. 1997) (explaining that the district court should have either denied the motion without prejudice or converted it to a summary-judgment motion allowing the parties to present additional materials). A defendant seeking judgment of collateral estoppel must show: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 247-48 (3d Cir. 2010). Although patent claims do not need to be identical for collateral estoppel to apply, "the differences between the unadjudicated patent claims and adjudicated patent claims" cannot "materially alter the question of invalidity." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

Collateral estoppel is inappropriate here. The claims of the '933 patent differ on their face in significant ways from the litigated claims. Based on the information available at this stage—the specification and file history of the '933 patent, and the decisions from the *Teva* action and the Chapman interference proceeding and the patents and application on which they are based—those differences are material to the patentability of the '933 patent claims. *See Ohio Willow Wood Co. v. Alps South, LLC*, C.A. No. 2:05-1039, 2012 WL 4322541, at *6-10 (S.D. Ohio Sept. 20, 2012) (refusing to apply collateral estoppel where the unadjudicated claims had a narrower scope than the adjudicated claims). Because those differences were not at issue in the prior proceedings and thus not actually litigated, collateral estoppel cannot apply.

In addition, with respect to the Chapman proceeding, as the district court in the *Teva* action explained, "even assuming that the invalid claims in the Chapman Application are

identical or substantially similar to the claims in issue in this action, the substantial difference between the legal standards applied prevents this Court from applying collateral estoppel." *Purdue*, 994 F. Supp. 2d at 411-13 (explaining that burden for invalidity in the interference was "preponderance of the evidence" but in a litigation is "clear and convincing evidence").

B. Product Claims 1 and 16 and Their Dependent Claims Are Not Subject to Collateral Estoppel

Mylan asserts that the validity of claims 1 and 16 (and their dependent claims) was already decided during prior adjudication of the low-ABUK patent claims. (Br. 10-16.) That is incorrect. Claims 1 and 16 do not recite the same products claimed in the low-ABUK patents. Although claims 1 and 16, like the adjudicated product-by-process claims in the low-ABUK patents, "claim an oxycodone hydrochloride composition with less than 25 ppm 14-hydroxy," (Br. 12), the '933 claims recite other, different limitations that have not been previously litigated and are meaningfully different from the adjudicated low-ABUK patent claims.

1. The 8α and 95% Limitations of Claims 1 and 16 Were Not Considered in the Prior Actions

As Mylan acknowledges (Br. 12), claims 1 and 16 of the '933 patent each have at least two limitations not present in any of the claims litigated in the *Teva* action: the claimed compositions "comprise," *inter alia*, (1) "8α" and (2) "at least 95% oxycodone hydrochloride." By contrast, the litigated claims of the '799 and '072 patents recite oxycodone API with low amounts of 14-hydroxy, wherein "a portion of the 14[-]hydroxy[] is derived from [8α]"; the litigated claims of the '800 patent similarly recite oxycodone API prepared according to a process in which oxycodone base contains 8α and the 8α is converted to 14-hydroxy. (Br. Ex. B.) And none of those claims recites the 95% limitation in any respect.

In its attempt to invoke collateral estoppel nonetheless, Mylan relies on the doctrine of inherency, arguing that the litigated claims "already encompassed (and certainly did not exclude)

products containing 8α." (Br. 13-14.) The inherency doctrine, however, is legally irrelevant here. Inherency is used in the context of whether *prior art* discloses a limitation; the question asked is whether an element is inherent in the prior art, not whether an element is inherent in a claim (or in the specification of the patent in question). *See*, *e.g.*, *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1319-21 (Fed. Cir. 2004). Mylan provides no support for applying inherency to determine the collateral-estoppel effect of adjudicated claims (which are not prior art).

Indeed, Mylan's use of inherency in this context is logically unsound. By definition, an independent claim "encompasse[s]" the subject matter of a dependent claim. 35 U.S.C. § 112 ¶ 4 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). Yet a dependent claim "shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282. Under Mylan's argument, however, these principles would be eviscerated, as a narrower, unadjudicated claim would be invalid by virtue of it being "encompassed by" a previously invalidated claim. Likewise unsound is Mylan's repeated invocation of the shared patent specification (Br. 12-14) to argue that the prior actions inherently adjudicated the limitations of the '933 patent claims. Individual claims, not patent specifications, are evaluated for validity, *see* 35 U.S.C. § 282; *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304, 1316 (Fed. Cir. 2002) ("When determining the validity of the claims of a patent, each claim must be separately considered[] . . . ."), and while the scope of a claim is defined in light of the patent specification, preferred embodiments in the specification do not ordinarily limit the claim, *see*, *e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323-24 (Fed. Cir. 2005). Thus, contrary to Mylan's suggestion, an unadjudicated claim is not "encompassed by" a previously adjudicated claim simply because the two share a patent specification.

But even if "inherency" were somehow relevant, it could not support collateral estoppel

here. For one, whether a limitation is inherently disclosed in the prior art to invalidate a claim is a question of fact. *See Toro*, 355 F.3d at 1320-21. That fact-based inquiry is inappropriate on a motion to dismiss, which tests the *legal* sufficiency of a claim. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"). For another, the doctrine of inherency, "originally rooted in anticipation, must be carefully circumscribed in the context of obviousness," and the proponent must "meet a high standard." *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). "[T]he limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Id.* at 1196. Mylan has hardly satisfied that test.

As for the **"8α" limitations**, those limitations were not "inherently" part of the low-ABUK claims or otherwise decided by the adjudication of those claims. The courts in the *Teva* action *disregarded* 8α in assessing obviousness of those claims on grounds inapplicable here.

First, the courts in the *Teva* action disregarded the 8α limitations at issue in that case on the ground that they were "process limitation[s]" in product-by-process claims. *Purdue*, 811 F.3d at 1354. That was based on legal principles specific to product-by-process claims. *Id.* Mylan refers to Purdue's disagreement with the *Teva* decision to disregard the 8α limitations in those claims (Br. 13-14), but collateral estoppel is based on what the Federal Circuit ruled, not what Purdue argued. Here, by contrast, Mylan does not dispute that claims 1 and 16 of the '933 patent are product claims (not product-by-process claims) and that their 8α limitation must be considered. (Br. 10-16; Br. Ex. A at 1-2.) Thus, although Purdue continues to disagree with the decision to disregard the 8α limitations in the low-ABUK patent claims, there is no legal basis to disregard any claim limitations here, and Mylan points to none.

Second, the Federal Circuit disregarded the 8α limitations in the *Teva* action on the view that the products recited in those claims did not concern 8α, but instead simply recited an oxycodone product with low amounts of 14-hydroxy, and thus Purdue's discovery of 8α was not necessary to those claimed inventions. *Purdue*, 811 F.3d at 1352-54; *see also Purdue*, 994 F. Supp. 2d at 405. Unlike those claims, claims 1 and 16 of the '933 patent expressly require 8α in the end product. Claims 1 and 16 recite an oxycodone product that "comprises" 8α. (Br. Ex. A.) Such limitations were not "encompassed" by the low-ABUK patent claims.

Further, when the 8α limitations of claims 1 and 16 are considered, they plainly impart patentable significance. In Mylan's words, 8α "was the whole point" of the related patents. (Br. 13.) The prosecution history of the '933 patent confirms the patentable significance of the 8α limitations in claims 1 and 16. The examiner allowed the claims at least in part because they require 8α, which was not known in the prior art and thus distinguished the claims from the cited art.[4] (Opp. Ex. 2, Notice of Allowability, at 2; Opp. Ex. 3, 3/4/2015 Response to Office Action, at 5-9.) Likewise, put in terms of "inherency," Mylan has not shown that the claimed product with 14-hydroxy "derived from 8α" or "converted" from 8α (as in the litigated claims) *necessarily* contains the 8α required by the '933 patent product claims. *See Advanced Fiber Techs., Trust v. J&L Fiber Servs.*, 751 F. Supp. 2d 348, 362-63 (N.D.N.Y. 2010) ("If the plate is '*preferably formed*' in a flat configuration, it is clearly not *necessarily formed* in that configuration initially."), *rev'd in part on other grounds*, 674 F.3d 1365 (Fed. Cir. 2012); *Toro*, 355 F.3d at 1320 (a "critical question for inherent anticipation" is whether "practicing the [prior

[4] Mylan's statement that 8α is "[a] known byproduct" of the oxycodone manufacturing process is misleading at best. (Br. 4.) As the district court expressly found, and the Federal Circuit did not disturb, at the time Purdue developed its low-ABUK inventions, "the prior art did not disclose the existence of 8α or teach that it converts to 14-hydroxy," and 8α's "very existence was unexpected." *Purdue*, 994 F. Supp. 2d at 396.

art] necessarily featured or resulted in [the claim limitation at issue].").

In short, contrary to Mylan's assertion, the *Teva* action did not decide the validity of "products containing 8α" or claims to "oxycodone with 8α." (Br. 13, 14.) That issue remains for this Court to decide for the first time.

As for the **95% limitations**, those, too, were not "encompassed" or "already covered by" the adjudication of the low-ABUK patent claims (Br. 12-13), which do not recite *any* percentage of oxycodone hydrochloride. Mylan cites to the disclosure in the specification that, "[p]referably, the oxycodone hydrochloride preparation . . . contains at least 95% oxycodone hydrochloride" or higher. (Br. 12 (quoting Br. Ex. 4, '072 patent, at 5:65-6:3).) A product that only "preferably" contains a certain amount of oxycodone hydrochloride does not *necessarily* contain that amount. *See Toro*, 355 F.3d at 1320. And while Mylan cites the district court's *Teva* decision for the proposition that the prior art disclosed the 95% limitation (Br. 12-13 (citing 994 F. Supp. 2d at 396-98)), neither there nor anywhere else does that decision discuss percentages of oxycodone in the prior art. Like the 8α limitation of claims 1 and 16 of the '933 patent, the 95% limitation has not been previously adjudicated and precludes collateral estoppel.

2. The Additional Codeinone Limitation of Claim 16 Was Not Considered in the Prior Actions

Claim 16 includes a third limitation that precludes collateral estoppel: its composition comprises "less than 5 ppm of codeinone." (Br. 15; Br. Ex. A.) Codeinone was never at issue in the *Teva* action (or in *Chapman*), and none of those adjudicated claims recites codeinone.

To assert collateral estoppel nonetheless, Mylan contends codeinone was "known in the art," seeking to characterize claim 16's codeinone limitation as only a slight difference that does not render the claim patentably distinct from the adjudicated low-ABUK claims. (Br. 15-16.) That is a fact issue premature to decide on a motion to dismiss. Even so, the available evidence

does not support Mylan's argument. Claim 16 recites a combination of elements—an oxycodone composition comprising 8α, a low amount of 14-hydroxy, *and* a low amount of codeinone—not codeinone solely. ('933 patent at 2:20-23, 6:51-54.) That combination is materially distinct from the low-ABUK patent claims. The *Teva* action did not address a combination comprising codeinone, much less in the particular limit claimed. *See Westwood Chemical, Inc. v. United States*, 525 F.2d 1367, 1380 (Ct. Cl. 1975) (Even if an additional element "is known in the prior art and does not alter the issue as to the differences between the claimed subject matter and the prior art, it is still necessary to assess the importance of the difference to the combination as a whole since it is from that standpoint that the obviousness determination must be made").

Mylan relies again on "inherency." Besides being legally improper, *see supra* Part I.B.1, Mylan's arguments are unsupported. Mylan argues that codeinone is "necessarily present" in the products claimed in the low-ABUK patents because the shared specification refers to codeinone. (Br. 16 (citing Br. Ex. 4, '072 patent at 6:46-49).) But the specification states only that the present invention "may" reduce other ABUKs such as codeinone; this does not establish that codeinone is *necessarily* present in the adjudicated claims, much less in the quantity claimed in claim 16, *i.e.*, "less than 5 ppm" codeinone. Indeed, Mylan does not even allege that the adjudicated low-ABUK claims inherently contain codeinone in that particular amount. Likewise, Mylan has not shown—and the *Teva* case did not adjudicate—that the specification's example of a way to test for codeinone means that the previously adjudicated claims inherently require codeinone. (*Cf. id.* (citing Br. Ex. 4, '072 patent at 31:20-34:54).) Indeed, the existence of a test for a substance does not mean the substance is necessarily present in the composition.

In short, Purdue has now claimed a reduced amount of codeinone in claim 16. Adjudication of the low-ABUK claims without this limitation does not control claim 16.

3. The Additional Limitations of the Dependent Claims Were Not Considered in the Prior Actions

Because claims 1 and 16 are materially different from the previously adjudicated claims, so are the claims that depend from them (claims 2-9 and 17-20, respectively). Moreover, certain dependent claims (claims 4-9 and 17-20) have additional limitations regarding the amount of 14-hydroxy that were not considered in the prior actions and further preclude collateral estoppel. To argue otherwise, Mylan again relies on "inherency," arguing that the litigated claims reciting "less than 25 [or 15 or 10] ppm 14-hydroxy[]" "already included" the additional limitations (*e.g.*, less than 5 ppm 14-hydroxy) recited in certain '933 dependent claims. (Br. 14-15.)

Again, inherency is inapplicable as a matter of law. Moreover, the factual premise of Mylan's argument is fundamentally flawed. Claims having limits of 14-hydroxy less than 5 ppm are *narrower* than claims having limits of 25 ppm. The adjudicated low-ABUK claims reciting "less than 25 ppm of 14-hydroxy" cover oxycodone hydrochloride that is *less pure* than the '933 claims reciting oxycodone hydrochloride with less than 5 ppm of 14-hydroxy. The *Teva* action did not address this narrower limitation and cannot support collateral estoppel. Moreover, Mylan ignores that dependent claims 5-9 and 18-20 have yet still different limitations—they bookend the amount of 14-hydroxy between "less than 25 ppm" and "lower" limits (floors) of 0.25 to 5 ppm. Mylan entirely fails to address these limitations. Those additional differences from the previously adjudicated claims further preclude collateral estoppel for these dependent claims.

C. Process Claim 10 and Its Dependent Claims Are Not Subject to Collateral Estoppel

Mylan's arguments for collateral estoppel as to claim 10 (and its dependent claims) should also be rejected. Mylan argues that, whether characterized as a product-by-process claim or a process claim, claim 10 "is directed to an oxycodone composition having less than 25 ppm 14-hydroxy—the same subject matter that was invalidated in the low-ABUK patents." (Br. 17.)

That is wrong.[5]

As an initial matter, claim 10 is plainly a process claim, not a "product" or "product-by-process" claim. Claim 10 recites "[a] process":

> 10. A *process* for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising *removing* 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and *converting* the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

('933 patent, claim 10 (emphasis added).) Accordingly, Mylan incorrectly suggests that "process limitations" added by claim 10 are irrelevant based on the *Teva* decision (and its reliance on *SmithKline*) to disregard process limitations in product-by-process claims. (Br. 17.) As with claims 1 and 16, that holding specific to product-by-process claims has no relevance to claim 10.

When claim 10 is properly understood as a process claim, the lack of collateral estoppel is plain. There has been no adjudication of that process. The *Teva* action did not adjudicate any process claims. Moreover, those courts disregarded 8α, rendering the various district-court findings unrelated to 8α, vaguely cited by Mylan (Br. 18), irrelevant. With respect to 8α, however, that court agreed "that with its knowledge of 8α Purdue had the capability to practice its claims in a way that would have been nonobvious. That is, Purdue could practice its claims by tailoring them to 8α." *Purdue*, 994 F. Supp. 2d at 407. Claim 10 is tailored in that fashion.

Chapman (Br. 17) is likewise irrelevant because, although those claims are process claims, they did not recite 8α. *See Purdue*, 811 F.3d at 1349 (citing *Chapman*, 315 F. App'x at 297). As the Federal Circuit suggested, process claims expressly directed to 8α—like claim 10

[5] Mylan states that Purdue "only asserts alleged infringement of claims 1 and 16" and suggests that claim 10 might not be relevant. (Br. 16 & n.18.) Purdue's complaint, however, is not limited to claims 1 and 16. (D.I. 1 at ¶ 36.) Indeed, Purdue's initial infringement contentions are not due until April 26, 2016. (D.I. 18 at 2.)

here—would likely be nonobvious. *See id.* (citing *Chapman*, 315 F. App'x at 297).

To the extent Mylan suggests that the validity of claim 10 has already been decided by a determination on the validity of process claim 57 of the '800 patent (unasserted in the *Teva* action), that is incorrect. (Br. 16 n.19.) The validity of claim 57 has not been decided. Although product-by-process claim 77 of the '800 patent, which was adjudicated in the *Teva* action, refers to claim 57, that does not render claim 57 invalid. Mylan once again ignores that the courts in the *Teva* action ignored process limitations, including the process steps of claim 57, and thus the *Teva* action did not actually decide the validity of claim 57. For the same reasons, the *Teva* action did not actually decide the validity of process claim 1 of the '800 patent.

Finally, Mylan has failed to show that any of the claims that depend on claim 10 are subject to collateral estoppel. Those claims (claims 11-15) add limitations, such as steps for "isolating" the oxycodone API. Mylan has not even attempted to show that these limitations are not materially different from the adjudicated claims.

D. Mylan's Other Arguments Are Unavailing

Mylan relies on the PTO's rejection of what issued as claims 1, 10, and 16 during prosecution of the '933 patent for obviousness-type double patenting over the low-ABUK patents. (Br. 9-10.) According to Mylan, the PTO "confirmed" that the '933 patent claims "are not patentably distinct" from the invalid low-ABUK patent claims. (*Id.*) For reasons explained above, that is incorrect. The '933 claims have different limitations from the adjudicated claims.

Nor can Mylan gain support from Purdue's response to the PTO's rejection, filing a terminal disclaimer. As Mylan's exhibit shows, Purdue expressly *disagreed* with the PTO's determination. (Br. Ex. 8.) Although Mylan makes unfounded accusations about Purdue's response being "attorney statement" and "gamesmanship" (Br. 10 & n.13), Mylan ignores clear precedent that a terminal disclaimer does not constitute acquiescence to the merits of a rejection.

As Purdue expressly cited to the PTO, the Federal Circuit has held that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." *Quad Environmental Techs. Corp. v. Union Sanitary District*, 946 F.2d 870, 874 (Fed. Cir. 1991) (cited in Br. Ex 8 at 2). Indeed, there was little incentive for Purdue to do anything but submit the terminal disclaimers. A terminally disclaimed patent is enforceable only as long as the full statutory term of the patent to which it is disclaimed, and so long as the patents are co-owned. The '933 patent and low-ABUK patents have the same priority date, so even without the disclaimers, they would have the same expiration date (setting aside any minor adjustments for reasons not relevant here). And Purdue, which has always owned the low-ABUK and '933 patents, has no incentive to split ownership of those patents, all of which cover Purdue's successful OxyContin® product.

Finally, none of Mylan's cases applying collateral estoppel based on previously adjudicated claims supports Mylan's motion. (Br. 7-8, 15.) In those cases, either there were no substantive differences at all between the adjudicated and unadjudicated claims, or any differences related to well-known features. *See Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1319-20 (Fed. Cir. 2015) ("[T]he routine incorporation of Internet technology . . . does not change the invalidity analysis"); *Ohio Willow Wood*, 735 F.3d at 1342 (It was "without dispute that the asserted claims . . . [were] substantially similar to the invalidated claims," and the former claims used "slightly different language to describe substantially the same invention"); *Bourns, Inc. v. United States*, 537 F.2d 486, 493-94 (Ct. Cl. 1976) (The patentee made "no argument at all" that the additional elements distinguish from the prior art and "offer[ed] not one word that suggests that either of [the additional] features contributed in any way to any of the stated objects of the patent, or that they are in any way

important to the combination set forth in the claims in which they appear"); *Westwood*, 525 F.2d at 1380 ("[S]uch minor differences as exist between the litigated claims and those here in issue are so insubstantial that the issues of validity under Graham v. John Deere[] must be considered to be the same"). As set forth above, Mylan has failed to show how claims 1, 10, and 16, which recite limitations that even the prior courts expressly found significant if claimed as in the instant manner, align with the facts of these cases.

II. MYLAN'S MOTION IS PREMATURE

A. Collateral Estoppel Is a Fact-Intensive Inquiry

Even apart from the substantive failings of Mylan's motion, Mylan's defense of collateral estoppel is, at the very least, premature given the limited record at this stage of the case. *Rycoline*, 109 F.3d at 886. Although Mylan cites decisions applying collateral estoppel to validity, none supports Mylan's request here. Each cited decision held unadjudicated claims invalid only after the opportunity for discovery and factual development relevant to those claims. *See Soverain*, 778 F.3d at 1313 (appeal); *Ohio Willow Wood*, 735 F.3d at 1341-43 (summary judgment); *Bourns*, 537 F.2d at 488 (summary judgment); *Westwood*, 525 F.2d at 1368-69 (summary judgment). The *Westwood* court, which considered extensive factual evidence (including expert testimony), noted the complexity of analyzing whether collateral estoppel applies to different claims in the context of obviousness: "The foregoing analysis has been considerably more thorough than is normally to be expected when issues of collateral estoppel are raised. In part, this is the necessary result of the conclusion that collateral estoppel may extend to nonlitigated claims." 525 F.2d at 1379. And none of Mylan's cases applied collateral estoppel to invalidate claims, like here, that could not have been litigated in the earlier case because they issued after the supposedly estopping judgment.

Mylan's citation to a non-patent case (Br. 8 (citing *M & M Stone Co. v. Pennsylvania*,

388 F. App'x 156 (3d Cir. 2010))—for the proposition that collateral estoppel can be decided on a motion to dismiss—is inapposite. As one court has explained, the question of whether collateral estoppel should apply to nonlitigated claims depends on "the issues of *fact* and law necessary to a resolution of the obviousness issue." *Bourns*, 537 F.2d at 492 (emphasis added).

B. The *Teva* Decision Is Still Subject to Further Review

At minimum, if the Court were inclined to find collateral estoppel, it should wait to decide Mylan's motion until after Purdue exhausts its rights in the *Teva* appeal. The Federal Circuit has yet to decide Purdue's pending petition for rehearing en banc, and if that petition is unsuccessful, Purdue intends to seek review by the Supreme Court. Case law supports waiting until the *Teva* appeal is fully resolved. *See, e.g.*, *Hewlett-Packard Co. v. Berg*, 61 F.3d 101, 105 (1st Cir. 1995) ("Indeed, a typical reason [for a stay] is the pendency of a related proceeding in another tribunal."); *Cephalon, Inc. v. Sandoz Inc.*, C.A. No. 10-123-SLR, 2011 WL 1750446, at *2-3 (D. Del. May 5, 2011) (granting stay in Hatch-Waxman patent case on the eve of trial, pending appeal of a prior decision holding the asserted patents invalid); *SmithKline Beecham Corp. v. Apotex Corp.*, C.A. No. 99-4304, 2004 WL 1615307, at *7 (E.D. Pa. July 16, 2004) (granting stay in Hatch-Waxman case pending appeal of prior invalidity ruling). Indeed, various Mylan entities, including Mylan Pharmaceuticals, Inc., recently made a similar request in this District, asking Judge Andrews to "refrain from taking further action on [their] pending motion to dismiss until after the Federal Circuit has had a chance to fully adjudicate" their rehearing petition in another case. Defendants' Letter, *Indivior Inc. v. Mylan Techs. Inc.*, C.A. No. 15-1016-RGA (D. Del. Mar. 30, 2016), D.I. 51 (attached as Opp. Ex. 4).

CONCLUSION

For the foregoing reasons, Mylan's motion should be denied. At minimum, decision on Mylan's motion should be deferred until the *Teva* appeal is finally resolved.

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 22, 2016, upon the following in the manner indicated:

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